REMARKS

Reconsideration of the present application in view of the above amendments and the following remarks is respectfully requested.

I. Status of the Claims

Claims 104-146 are pending in this application. In the Office Action mailed on February 26, 2004, claims 104-146 were rejected. Claims 128-136 have been canceled, claims 104, 110, 111, 113, 115, 116, 118, 120, 121, 123, 124, 126, 127, 138, 140, 141, 143, 145, and 146 have been amended, and new claims 147-170 have been added.

II. Objection Under 35 U.S.C. §132 and Rejection Under 35 U.S.C. §112

The Examiner objected to the Amendment filed on November 28, 2003 under 35 U.S.C. §132, stating that it added new matter into the disclosure. Specifically, the Examiner stated that claims 109, 110, 122, 123, 125, 126, 128-132 contain information which is neither included nor implied in the original specification. Similarly, the Examiner rejected claims 109-123, and 125-146 under 35 U.S.C. §112 as containing subject matter not described in the specification.

With respect to claims 109 and 125, the Examiner objected to the language "wherein at least two sensors" and "physiological sensors and contextual sensors." Support for this language can be found in the specification at page 5, lines 3-5 ("Sensor device 10, includes one or more sensors, which are adapted to generate signals in response to physiological characteristics of an individual"), page 11, lines 1-6 ("Sensor device 10 may include one or more sensors for generating signals in response to contextual characteristics relating to the environment surrounding the individual, the signals ultimately being used to generate the type of data

described above. Such sensors are well known, as are methods for generating contextual parametric data such as air quality, sound level/quality, ambient temperature and global positioning.), and page 11, lines 17-19 ("A digital signal or signals representing certain physiological and/or contextual characteristics of the individual user may be used by microprocessor 20 to calculate or generate data indicative of physiological and/or contextual parameters of the individual user."). Accordingly, Applicants requests that the objection and rejection of the subject claims be withdrawn.

With respect to claims 110 and 126 (and 111 and 127, although not specifically identified by the Examiner), the objected to language has been deleted from the claims. Applicants have done so to expedite the prosecution of the present application, and are not admitting that the objected to language lacked support. Accordingly, Applicants request that the objection and rejection of the subject claims be withdrawn.

With respect to claim 122, the Examiner objected to the language "aggregating said data indicative of one or more measured parameters with data collected from a plurality of individuals to create aggregate data." Support for this language can be found in the specification at page 21, lines 13-18 ("Third parties such as insurance companies or research institutions may be given access, possibly for a fee, to certain of the information stored in mirror network storage device 120. Preferably, in order to maintain the confidentiality of the individual users who supply data to central monitoring unit 30, these third parties are not given access to such user's individual database records, but rather are only given access to the data stored in mirror network storage device 120 in aggregate form."). Accordingly, Applicants request that the objection and rejection of the subject claim be withdrawn.

With respect to claim 123, the Examiner objected to the language "the step of creating aggregate data reports based on said aggregate data." Claim 123 has been amended to read "the step of creating reports based on said aggregate data." Support for this language can be found in the specification at page 21, line 13 to page 22, line 6 ("Third parties such as insurance companies or research institutions may be given access, possibly for a fee, to certain of the information stored in mirror network storage device 120. Preferably, in order to maintain the confidentiality of the individual users who supply data to central monitoring unit 30, these third parties are not given access to such user's individual database records, but rather are only given access to the data stored in mirror network storage device 120 in aggregate form. Such third parties may be able to access the information stored in mirror network storage device 120 through the Internet using a conventional browser program.... In addition, the third parties can choose from a series of prepared reports that have information packaged along subject matter lines, such as various demographic categories."). Accordingly, Applicants request that the objection and rejection of the subject claim be withdrawn.

Applicants have canceled claims 128-136, which contained language objected to by the Examiner. Applicants have done so to expedite the prosecution of the present application, and are not admitting that the objected to language lacked support.

III. Rejection Under 35 U.S.C. § 103

The Examiner rejected claims 104-112, 114, 117, 119, 124-127, 137, 139, 142 and 144 under 35 U.S.C. § 103(a) as being unpatentable over Brown, United States Patent No. 5,951,300, ("Brown300") in view of Alyfuku et al., United States Patent No. 5,410,471. The Examiner rejected claims 113, 118, 138 and 143 under 35 U.S.C. § 103(a) as being unpatentable over

Brown300, in view of Alyfuku et al. and further in view of Korenman et al., United States Patent No. 6,067,568. The Examiner rejected claims 115-116, 120-121, 140-141, and 145-146 under 35 U.S.C. § 103(a) as being unpatentable over Brown300, in view of Alyfuku et al. and Korenman et al., and further in view of Pottgen et al., United States Patent No. 5,813,994 and Nasiff, United States Patent No. 4,757,453. The Examiner rejected claim 122 under 35 U.S.C. § 103(a) as being unpatentable over Brown300 and Alyfuku et al. and further in view of et al., United States Patent No. 6,032,119 ("Brown119"). The Examiner rejected claim 123 under 35 U.S.C. § 103(a) as being unpatentable over Brown300, Alyfuku et al. and Brown119, and further in view of Brown et al., United States Patent No. 5,913,310 ("Brown310"). The Examiner rejected claims 128-136 under 35 U.S.C. § 103(a) as being unpatentable over Brown300 and Alyfuku et al., and further in view of McIlroy et al., United States Patent No. 5,583,758.

With respect to claims 104 and 124, the Examiner stated that Brown300 teaches a method for assisting an individual to monitor, control and modify certain aspects of the individual's physiological status according to a preset physiological status goal, the method comprising establishing the physiological status goal according to certain preselected physiological parameters of the individual, using data indicative of one or more measured parameters to compare target parameters to actual parameters, and, in the case of claim 104, providing the status information to the individual, and, in the case of claim 124, providing to the individual a treatment plan. The Examiner stated that Brown300 does not explicitly disclose affixing a physiological monitoring device in proximity to the body of the individual and generating data indicative of one or more measured parameters of the individual using the device. The Examiner stated, however, that Alyfuku et al. teaches affixing a physiological monitoring device in proximity to the body of the individual and generating data indicative of one or more measured

parameters of the individual using the device. The Examiner thus concluded that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method disclosed in Brown300 to include affixing a physiological monitoring device in proximity to the body of the individual and generating data indicative of one or more measured parameters of the individual using the device as taught by Alyfuku et al.

Claims 104 and 124 have been amended to recite "wearing a wearable physiological monitoring device on the body of the individual" and "generating data indicative of one or more measured parameters of an individual using said wearable physiological monitoring device." In contrast, Alyfuku et al. describes a number of household appliances, such as a toilet, a bed, a bathtub, an exercise bike, and an easy chair, having sensors incorporated therein for measuring individual physiological parameters when an individual comes into proximity and/or physical contact with the fixed appliance, and thus the sensor or sensors. Alyfuku et al. does not describe a wearable physiological monitoring device as described in the present application and claimed in amended claims 104 and 124. Furthermore, neither Alyfuku et al. nor any of the other references cited by the Examiner teaches or suggests the use of a wearable physiological monitoring device in a method for assisting an individual to monitor, control and modify certain aspects of the individual's physiological status according to a preset physiological status goal as recited in claims 104 and 124. Instead, Alyfuku et al. and each of the other references cited by the Examiner that includes a monitoring device merely describe measuring and collecting certain physiological parameters using such devices.

On this subject, the Federal Circuit has long held that "[w]hen a rejection depends on a combination of prior references, there must be some teaching, suggestion, or motivation to

combine the references." In re Rouffet, 149 F.3d 1350, 1355. The Federal Circuit has further stated:

> '[V]irtually all inventions are combinations of old elements.' Therefore an Examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents by solely finding prior art corrollaries for the claimed elements would permit an Examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be 'an illogical and inappropriate process by which to determine patentability.'

In re Rouffet, 149 F.3d at 1357 (citations omitted). In accord with these principles, Applicants respectfully submit that if the Examiner were to reject claims 104 and 124 under 35 U.S.C. § 103(a) by combining Brown300 with a reference that merely teaches a wearable monitoring device (of which there are many) and that does not also teach or suggest using the wearable monitoring device to monitor, control and modify physiological status according to a preset physiological status goal as claimed, the Examiner would be using the claimed invention as a blueprint to piece together prior art elements to defeat the patentability of the invention claimed in claims 104 and 124. As stated in In re Rouffet, this would be improper.

Accordingly, because the cited references do not teach or suggest the method as recited in amended claims 104 and 124 which include the limitation a wearable physiological monitoring device, Applicants submit that such claims are allowable. Furthermore, because claims 105-123 and 147-149 depend from claim 104, and claims 125-127, 137-146, and 150-152 depend from claim 124, they are likewise believed to be allowable for the same reasons.

In addition, the Examiner rejected claims 105-108 by stating that Alyfuku et al., in Figure 3A, provides a list of categories. Claim 105 recites "wherein said physiological status

goal comprises a plurality of categories," claim 106 recites "wherein said status information is determined and provided with respect to each of said categories," and claim 107 recites "wherein said categories relate to two or more of nutrition, activity level, mind centering, sleep, and daily activities." In other words, as claimed, the categories relate to the specific physiological status goal and the status information that is provided relating to that goal. In contrast, the categories listed in Figure 3A of Alyfuku et al. are categories of things that may be measured by the various appliances described in Alyfuku et al., and not categories of the physiological status goal or any status information relating thereto. Thus, Applicants respectfully submit that these claims are allowable over the cited references for this additional reason.

Applicants have not at the present time addressed the Examiner's other specific rejections relating to the claims depending from independent claims 104 and 124 because, as set forth above, Applicants believe that those claims are allowable by virtue of their dependence on claims 104 and 124. Applicants, however, reserve the right to address these specific rejections in the future should it become necessary.

IV. New Claims

New claims 153 and 157 each recite a method for assisting an individual to monitor, control and modify certain aspects of the individual's physiological status according to a preset physiological status goal including steps of "wearing a wearable physiological monitoring device on the body of the individual, said wearable physiological monitoring device having at least two sensors, said at least two sensors being two of a body motion sensor adapted to generate data indicative of motion, a skin conductance sensor adapted to generate data indicative of the resistance of said individual's skin to electric current, a heat flux sensor adapted to generate data

indicative of heat flow, a body potential sensor adapted to generate data indicative of heart beats or muscle or brain activity of said individual, and a temperature sensor adapted to generate data indicative of a temperature of said individual's skin, said wearable physiological monitoring device generating at least two of said data indicative of motion, said data indicative of resistance of said individual skin to electric current, said data indicative of heat flow, said data indicative of heart beats or muscle or brain activity and said data indicative of a temperature of said individual skin when worn by said individual" and "generating data indicative of one or more measured parameters of said individual using at least two of said data indicative of motion, said data indicative of resistance of said individual's skin to electric current, said data indicative of heat flow, said data indicative of heart beats or muscle or brain activity and said data indicative of a temperature of said individual's skin." New claim 153 further includes the step of "using said data indicative of one or more measured parameters to determine status information indicative of the relative degree of achievement of said individual's performance with relation to said physiological status goal," and new claim 157 further includes the step of "using said data indicative of one or more measured parameters to determine the relative degree of achievement of said individual's performance with relation to said physiological status goal." None of the references cited by the Examiner include a wearable physiological monitoring device including the at least two specified sensors recited in new claims 153 and 157 or a method utilizing such a physiological monitoring device to monitor, control and modify physiological status as recited in new claims 153 and 157. Korenman (cited by the Examiner) describes a device that includes only a galvanic skin response sensor, Nasiff (cited by the Examiner) describes a device that includes only piezoelectric transducers for measuring body motion and activity, and Pottgen et al. (cited by the Examiner) describes a device that includes only a heat flow sensor. As a result,

in accordance with the Remarks herein, Applicants submit that new claims 153 and 157, and the claims depending therefrom, are allowable over the cited references (Applicants note that claims 113, 118, 138, 143, 149 and 152 contain limitations similar to those in claims 153 and 157 and therefore are likewise allowable). No new matter has been added in claims 153 and 157.

In addition, new dependant claims 154 and 158 each recite that the wearable physiological monitoring device includes five specific sensors, namely a body motion sensor adapted to generate data indicative of motion, a skin conductance sensor adapted to generate data indicative of the resistance of the individual skin to electric current, a heat flux sensor adapted to generate data indicative of heat flow, a body potential sensor adapted to generate data indicative of heart beats or muscle or brain activity of the individual, and a temperature sensor adapted to generate data indicative of a temperature of the individual's skin. New dependent claims 154 and 158 further recite that the data indicative of each of the one or more measured parameters is generated using at least two of the data indicative of motion, the data indicative of resistance of the individual's skin to electric current, the data indicative of heat flow, the data indicative of heart beats and the data indicative of a temperature of the individual's skin as measured by the recited sensors. As was the case with new claims 153 and 157, none of the references cited by the Examiner describes a wearable physiological monitoring device including the sensors specified in new claims 154 and 158 or a method wherein one or more measured parameters are generated using the sensor data as recited in new claims 154 and 158. Accordingly, Applicants respectfully submit that new claims 154 and 158 are allowable over the cited references for this additional reason. No new matter has been added in claims 154 and 158.

Claims 155 and 159 depend from new claims 153 and 157, respectively, and each recite "said at least two sensors being said body motion sensor and said heat flux sensor, wherein said

one or more measured parameters comprises data relating to calories burned and is generated using at least said data indicative of motion and said data indicative of heat flow." In the Office Action mailed on February 26, 2004, the Examiner cited Pottgen et al. and Nasiff as references that describe devices that measure calories burned, also known as energy expenditure. Nasiff describes a device that utilizes four piezoelectric transducers, one for each arm and one for each leg, to measure body motion and activity and uses that information to calculate energy expenditure. Pottgen et al. describes a device that includes a heat flow sensor for measuring heat flow and uses the heat flow information to calculate energy expenditure. None of the references describes a wearable physiological monitoring device that includes both a body motion sensor and a heat flux sensor wherein data relating to calories burned or energy expenditure is generated using both data indicative of motion as measured by the body motion sensor and data indicative of heat flow as measured by the heat flux sensor as recited in new claims 155 and 159. Accordingly, Applicants respectfully submit that new claims 155 and 159 are allowable over the cited references for this additional reason (Applicants note that claims 115, 120, 140, and 145 contain limitations similar to those in claims 155 and 159 and therefore are likewise allowable). No new matter has been added in claims 155 and 159.

CONCLUSION

Based on the foregoing remarks, Applicants respectfully submit that claims 104-127 and 137-170 are in condition for allowance.

If a telephone conference would facilitate prosecution of this application in any way, the Examiner is invited to contact the undersigned at the number provided.

Respectfully submitted,

METZ LEWIS LLC

By _____

Philip E. Levy, 40,700
11 Stanwix Street, 18th Floor
Pittsburgh, Pennsylvania 15222
Attorneys for Applicant

(412) 918-1110